

Notice of Allowability

Application No.

09/811,842

Examiner

David A. Lambertson

Applicant(s)

LINK ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the request for continued examination filed 13 October 2003.
2. ☒ The allowed claim(s) is/are 53-74.
3. ☒ The drawings filed on 05 June 2001 and 24 February 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| 3 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____ | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

EXAMINER'S AMENDMENT

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 13, 2003 has been entered.

Information Disclosure Statement

The information disclosure statement filed October 13, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Specifically, several references were not present in the file. Those references have been crossed out on the corresponding form PTO-1449, and indicated as "not provided." In addition, a number of references had already been considered on the record, and those references are also crossed through and indicated as "duplicates." The references that were not previously considered and present in the file have been initialed, and a copy of the signed form PTO-1449 has been attached to this Office Action.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

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1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David W. Clough, Ph.D. on December 18, 2003.

The application has been amended as follows:

In the specification, please amend the first line of the specification as follows:

This application claims benefit under 35 U.S.C. § 119(e) of provisional application 60/190,678 filed March 20, 2000 and provisional application 60/198,722 filed April 20, 2003.

Please amend the claims as follows:

53. A method for elucidating a protein expression profile of a test cell line or group of cells, the method comprising:

(A) randomly introducing into the genome of a cell or group of cells a promoterless polynucleotide construct, the construct comprising in a 5' to 3' orientation:

- i) a splice acceptor consensus sequence;
- ii) the complementary sequence of a type IIS restriction enzyme recognition sequence;
- iii) an oligonucleotide sequence encoding assayable marker peptide; and
- iv) a polyadenylation sequence;

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(B) wherein said promoterless polynucleotide construct when introduced into an actively expressed gene[s] results in the generation of a truncated cellular protein fused at its C-terminal truncated end to the marker peptide; and

[v)] i) identifying those cells expressing said marker peptide fused to said truncated cellular protein;

[vi)] ii) determining the identity of the truncated proteins to which the marker peptide is fused in each group of sorted cells,

thereby elucidating a protein expression profile of a test cell line or group of cells.

54. The method of claim 53 further comprising sorting cells identified in step [v)] (B)(i) into subpopulations based on their different levels of expression of said marker peptide.

55. The method of claim 53 wherein the identity of the protein to which the marker peptide is fused is determined using a ~~method selected from the group consisting of 5' Rapid Amplification of cDNA Ends (5' RACE) and Serial Analysis of Viral Integration (SAVI).~~

57. A method to identify differentially expressed proteins in two different populations of cells, the method comprising:

(A) randomly introducing into the genomes of a reference group of cells and into the genomes of a test group of cells a promoterless polynucleotide construct, wherein the construct comprises in a 5' to 3' orientation:

i) a splice acceptor consensus sequence:

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ii) the complementary sequence of a type IIS restriction enzyme recognition sequence;

ii) an oligonucleotide sequence encoding assayable marker peptide; and

iv) a polyadenylation sequence;

(B) thereby generating a population of randomly truncated cellular proteins fused at their C-terminal truncated end to the marker peptide; and

[v)] i) sorting both groups of cells into subpopulations of cells based on their differential expression levels of the marker peptide;

[vi)] ii) determining the identity of the fusion proteins generated in each subgroup of sorted cells ~~by following one of the following procedures;~~ and

[vii)] iii) comparing by statistical methods the protein expression profiles obtained for the test group of cells against the protein expression profiles obtained for the reference group of cells,

thereby identifying differences in the expression levels of fusion proteins among the two groups of cells.

58. The method of claim 57 wherein the identity of the protein to which the marker peptide is fused is determined by ~~5' RACE~~ or SAVI.

67. The methods of claims 53-57 or 58 wherein ~~the protein-coding sequence~~ marker peptide is an epitope recognized by fluorescently or enzymatically labeled antibodies.

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68. The methods of claims 53-57 or 58 wherein the marker peptide ~~encoded by the~~ polynucleotide requires interaction with another protein in order to generate a fluorescent signal.

72. The methods of claims ~~53-57~~ 55, 56 or 58 wherein following amplification of the one or more extended cDNA fragments, and prior to cloning and sequencing the one or more CDNA fragments, the fragments are ligated together to form a concatenated molecule.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson, Ph.D.
AU 1636



JAMES KETTER
PRIMARY EXAMINER